STATEMENT OF WORK
PR-HQ-02-11601
"EMRAD Risk Assessment Support Contract-Office of Solid Waste"

I. INTRODUCTION

For this effort, a contract is needed to provide technical support to the Office of Solid Waste (OSW) for assessing risks from chemicals that are released from hazardous and non-hazardous waste management units. These assessments are necessary to determine if practices during the management, transfer, handling, storage, treatment or disposal of solid or hazardous waste will result in adverse effects on human health and ecological systems due to exposure to the wastes. In addition, technical support is necessary in determining the benefits and relative risk of various types of treatment and disposal alternatives. The scope of work is extensive and includes a variety (both in scope and duration) of tasks that shall be require multi-disciplinary and highly specialized expertise.

Specifically, the contractor shall provide support services to the Environmental Protection Agency ("EPA" or "the Agency") for the development and implementation of methods or models to predict the release, dispersion, deposition, exposure, transport, fate, and risks of chemicals disposed of, or managed in, industrial or municipal settings. Support is also necessary for collecting, accessing, and analyzing scientific information, and, following EPA review and approval, communicating this information to the EPA regions, the States, the public, and regulated community. Support is also needed in having technical work products scientifically peer reviewed. OSW emphasizes the quality of its work products and consequently stresses quality assurance and quality control in all aspects of the work.

To support EPA's assessment of risks associated with waste programs, the contractor shall provide a team of experts with risk assessment expertise in a variety of fields. The expertise needed for each task may include (but is not limited to) toxicology; microbiology; pharmacokinetics; chemistry; biochemistry; hydrology; biology; meteorology; ecology; statistics; engineering; soil science; computer programing; economics; hydrogeology; data-base management; and geochemistry.

II. BACKGROUND

The Solid Waste Disposal Act, as amended by the Resource Conservation and Recovery Act of 1976 (RCRA) and the Hazardous Waste and Solid Waste Amendments of 1984 (HSWA), requires the EPA to oversee a program that ensures that the management of solid and hazardous waste does not pose a risk to human health and the environment. Within EPA, OSW is involved in a variety of activities to support and develop hazardous waste (Subtitle C) and non-hazardous waste (Subtitle D) regulatory and non-regulatory actions. Specific regulations for carrying out RCRA are set forth in the Code of Federal Regulations (40 CFR 256 to 268 and 270 to 272).

OSW is involved in a variety of activities to support, expand, modify, assess and implement the solid and hazardous waste regulations. Additionally, these statutes also require several special reports to Congress. In order to determine if management practices used in the management of solid and hazardous waste is protective of human health and the environment, EPA uses various methodologies. EPA is responsible for: method sampling development and evaluation; data gathering and analysis; assessment of potential exposures and risk; quality assurance and quality control; feasibility studies for regulatory development; development of permits for hazardous waste facilities and other aspects of implementing Subtitle C and D of RCRA.

III. SPECIFIC WORK AREAS

The contractor shall, during the period of performance of the contract, provide the necessary Level-of-Effort (LOE) and all other related services to carry out the specific work assignments issued by the Contracting Officer in accordance with Clause B.2 of the Schedule entitled "Work Assignments."

The contractor shall provide up-to-date experience, knowledge and expertise in waste management techniques and analytic methodologies to develop new or modify existing EPA models and methods that will be used to identify potential risk resulting from treatment, storage and disposal of solid or hazardous waste. The contractor shall possess the capability of running new and existing data on EPA models. The contractor may be asked to perform tasks in the following general categories:

A. Risk Assessment Development;
B. Toxicological Summary Development;
C. Risk Model/Method Development;
D. Information Gathering/Analysis;
E. Document Preparation**;**
F. Regulatory Impact Analysis Support; and
G. Other Technical Support

The contractor shall provide recommendations and options to EPA on technical issues that are supported and documented by its underlying analysis. EPA will, however, make the final decisions with regard to the implementation of the recommendations. EPA will make all the decisions with regard to policy issues[1] that may arise. All materials prepared under this contract by the Contractor will be reviewed, revised and finalized, and approved by EPA prior to their use or distribution. EPA shall retain ownership of all materials prepared under this contract.

[1] For purposes of this statement of work, "policy issues" include any aspect of technical or scientific analysis or evaluation for which available information and well established convention do not clearly support one approach as most appropriate, thereby requiring a choice approach from among two or more possibilities. The contractor shall identify to EPA the policy issues arising in the course of work so that choices in the approach can be made.

All contractor deliverables under this contract shall be accompanied by a disclosure statement describing the deliverable and affirmatively stating that the information contained in the deliverable is of Contractor's origin and should not be construed as Agency policy, position or decision. In addition, all contractor data will be reviewed, revised or approved by the Agency prior to use in Agency documents. All contractor final documents shall include a bibliography identifying data sources used and publications relied upon in creating the document. Copies of all bibliographic items shall be provided to EPA when requested.

In all cases, the Contractor shall clearly identify its personnel as Contractor employees by means of clearly marked badges, or in E-mail or telephone introductions, so they will not be mistaken for Agency employees.

The Contractor shall assist EPA in performance of the following types of tasks:

Task 1: Risk Assessment Development

The contractor shall conduct environmental and human health analyses of waste management practices and problems relevant to RCRA managed wastes and other related environmental programs. The contractor shall provide qualitative and quantitative assessments of the potential environmental and human health impacts associated with actual to hypothetical waste management practices using methods and models ranging in complexity from site-specific to national screening-level and single medium to multi-media. These analyses may target plant, industry, local, regional, state, or national sectors. The contractor may be required to conduct validation and verification studies on the risk analysis. The contractor shall ensure that all analyses prepared under this contract are technically accurate, defensible, free of errors (e.g., data entry, methodology), and editorially correct (e.g., free of typographic and grammatical errors).

To support this task, the contractor may use or update existing risk methods or models, or may be required to develop new methods or models that:

- calculate or simulate the release of the contaminant from various waste management operations to different media (air, soil, surface water, groundwater);
- calculate or simulate the fate of the contaminants in various media (i.e., partitioning, hydrolysis, degredation);
- calculate or simulate transport of contaminants in the groundwater, including one-dimensional, two-dimensional, and three-dimensional models for aqueous and/or non-aqueous phase contaminants;
- calculate or simulate the contaminants' atmospheric fate and transport of gaseous, vapor-bound, and particulate-bound, air emissions from waste management operations;
- calculate or simulate the fate and transport of contaminants across land through erosion and run-off;
- calculate or simulate the fate and transport of contaminants in surface water;

- calculate or simulate the fate of contaminants in biological systems (i.e., plants and animals) including the uptake from soil, water, air, and diet;
- calculate or simulate exposures to human receptors and/or ecological receptors;
- estimate risks/hazards to human and/or ecological receptors;
- calculate or simulate multi-media (e.g., groundwater, surface water, air, and soil) fate and transport; and
- speciate metals for fate and transport simulations or calculations.

The contractor shall also provide technical and regulatory support that includes the following:

- support for human and ecological risk characterization from various media, and covers a variety of constituents and mixture, exposure duration, and direct and indirect exposure pathways, which may include ground water ingestion; soil ingestion; soil erosion and runoff; inhalation; and food consumption (*e.g.*, fish ingestion, beef and diary products, and agricultural crops). The support shall describe the scope of the assessment, expresses the results clearly, identifies the major assumptions and uncertainties, identifies the reasonable alternative interpretations, and separates scientific conclusions from policy judgments.

- support in areas related to waste management practices and operating procedures, and in modification of these practices and procedures as related to changes in hazardous waste regulations; and,

- support in areas of waste characterization, generation, minimization, treatment, reclamation, disposal, and releases resulting from waste management practices.

Task 2: Toxicological Summary Development

In some cases, constituents or chemicals of concern do not have a current toxicity value that has been agreed upon by the Agency. Consequently, the contractor shall be required to develop provisional toxicity benchmarks. In some cases, these provisional numbers will become part of the Agency Integrated Risk Information System (IRIS) process. To accomplish this task, the contractor shall review, analyze, and prepare summary reports on human health and ecological toxicological studies which are comprised of tests and supporting documentation for specific chemicals or classes of chemicals. Examples of these are acute, chronic, and subchronic oral, inhalation and ecological toxicity testing. In addition, the contractor shall review, analyze, and prepare summary reports on pharmacokinetics and metabolic studies to determine the body burden of the substance, the duration of the toxicant in the body following exposure, the time course of its elimination from the body, and the relationship between the various routes of exposure. In some cases, the contractor shall be required to use structure activity relationships to estimate potential hazard identification of the chemical. The contractor shall ensure that all summaries prepared under this contract are technically accurate, defensible, free of errors (e.g.,

data entry, methodology), and editorially correct (e.g., free of typographic and grammatical errors)

The toxicological summaries shall focus on:

- determining the quality of the toxicological tests conducted and the quality of the data generated compared to Agency guidelines;
- supporting the adequacy of the technical findings and interpretations for hazard identification and dose-response;
- identifying the appropriateness of the studies for use in estimating reference doses, carcinogenic slope factors and ecological toxicity reference values; and
- identifying the strengths, weaknesses and uncertainties of the recommended approach.

The contractor shall recommend, where appropriate, interim or provisional chemical-specific reference values (*e.g.*, reference doses, slope factors, ecological toxicity reference values). In certain instances, the contractor shall be required to put the provisional toxicity benchmark into format for inclusion in the IRIS process.

Task 3: Risk Model/Method Development and Support

The contractor shall undertake the necessary conceptual development, literature review, technical evaluation, and data assembly to provide support for the development, modification, and application of human health or ecological risk assessments. The contractor shall assist EPA in determining the analytical framework suited to provide support for the development and maintenance of risk information systems for human health and ecological effects for chemicals of concern. The contractor shall conduct the appropriate testing to ensure the accuracy of the method or code. The contractor may also be required to do validation and verification studies on new or existing EPA models or methods. The contractor shall ensure that all analyses prepared under this contract are technically accurate, defensible, free of errors (e.g., data entry, methodology), and editorially correct (e.g., free of typographic and grammatical errors).

Task 4: Information Gathering/Analysis

The contractor shall collect data relevant to the technical analyses from available sources and identify areas where additional data are needed. Information to be collected shall support analyses for chemical hazard identification; waste characterization; fate and transport of chemicals or waste constituents; facility site assessments, including waste management practices; and evaluating health and ecological hazards and exposures.

In the course of collecting data from an individual facility, the contractor shall inform the business that they may assert a RCRA Confidential Business Information (CBI) claim. The contractor will execute an agreement on the limitation of use of any RCRA CBI obtained. Before receiving any CBI, the contractor's must have it's site approved by an on-site inspection conducted by EPA. Any individual with access to RCRA CBI shall receive a RCRA CBI

clearance. The contractor shall maintain a logging system and physical security system for all RCRA CBI received. The contractor will follow established procedures for transmitting RCRA CBI.

The contractor shall provide the support through the following activities:

- conducting literature searches;
- developing and conducting surveys;
- compiling, analyzing, and summarizing questionnaire data;
- acquiring and adapting fate, transport, and risk assessment models and methods;
- developing and evaluating protocols for sampling, testing and analyzing data;
- designing and reviewing sampling plans;
- reviewing and assessing data quality; and
- developing case studies and documenting damage incidents.

The contractor shall also provide technical and regulatory analysis support that includes the following:

- exercises to validate existing models and methods used in risk assessment. Validation efforts may include: collecting field data to compare to modeled or calculated results; identifying, collecting, reviewing, and summarizing field data on contaminants in various media to compare to modeled or calculated results; and benchmarking models with other models;

- statistical analyses of input and output data including: variability and uncertainty in probabilistic results; develop statistical basis for probabilistic approaches; analyze and develop correlations among parameters used; and develop national, and regional distributions of environmental, waste management, cost, and economic parameters used for models;

- benefits analyses (*e.g.*, pollutant loading reductions, energy savings) and relative risk estimates (*e.g.,* compare the risks of various treatment and disposal options) related to hazardous waste regulations and non-regulatory alternatives; assessing the impact of proposed and final regulations and policies on the regulated and non-regulated community; and identifying areas where regulations and policies may need to be modified to reduce impacts and improve practicability;

- waste management practices and operating procedures, and in modification of these practices and procedures as related to changes in hazardous waste regulations;

- waste characterization, generation, minimization, treatment, reclamation, disposal, and releases resulting from waste management practices;

- support for the development, modification, and application of risk characterization models; and

- support for the development and maintenance of information systems for human health and ecological effects for chemicals of concern.

Task 5: Document Preparation

The contractor shall provide technical support for document preparation and revision and ensure that the products are responsive, timely, and of high quality to meet the requirements of the Agency. The contractor shall ensure that all documents prepared under this contract are technically accurate, defensible, free of errors (e.g., data entry, methodology), and editorially correct (e.g., free of typographic and grammatical errors). All supporting information shall be referenced and made available if requested. The types of documents that shall be prepared include:

- background documents to support OSW's rulemaking decisions;
- reports or special studies regarding waste or related environmental programs;
- draft technical guidance documents to assist in the implementation of hazardous and non-hazardous waste programs;
- issue papers on human and ecological effects;
- reports on specialized testing for selected chemicals;
- technical appendices that specify detailed information upon which analyses are based;
- peer review summary documents that specify recommendations from independent peer reviewers;
- technical materials and information reports which, following EPA editing and approval, will be distributed to interested parties (*e.g.*, industry, state agencies, environmental groups);
- user guides or manuals accompanying software products developed; and
- provide technical information in EPA specified report format in the areas mentioned in Tasks 1 through 4 above, and 6 below.

An important part of OSW's notice and comment process is the review and analysis of public and peer review comments and the subsequent response to those comments. The contractor shall compile, review characterize, and recommend possible responses to these comments for EPA consideration, according to guidance specified in the work assignments. EPA will make the final decision as to what recommendations to include in its final response to comments.

Task 6: Regulatory Impact Analysis Support

The contractor shall provide technical support to OSW in the development of methodologies for analyzing the costs, benefits, and impacts of waste related regulations and policies. This work may include providing technical assistance to EPA in the identification and

analysis of regulatory options, the development of regulatory flexibility analyses, voluntary programs, and information collection requests. This work may involve collecting all pertinent data relevant to these analyses from all available sources and providing technical assistance to EPA in identifying additional data needs. The contractor shall also provide administrative and data information gathering support for OSW's preparation of required analyses to support regulatory efforts such as requirements under the Regulatory Flexibility Act (RFA), the Small Business Regulatory Enforcement Fairness Act (SBREFA), the National Technology Transfer and Advancement Act (NTTAA), and the Unfunded Mandate and Reform Act (UMRA).

Task 7: Other Technical Support

Other technical support the contractor shall provide includes:

- coordination and facilitation of roundtables, public meetings, and dialogue sessions with the regulated community, environmental groups, and state regulators;
- training support services on the use of any software developed under this contract;
- training support services including the development of training modules for risk related methodologies or models;
- technical review of regional site-specific risk assessments;
- technical scientific editing of prepared documents;
- technical support for the OSW Quality Assurance (QA) program, particularly in the area of QA sampling and analysis plans and QA methods review;
- statistical analysis and review of assessments conducted;
- technical analyses of survey results;
- capability to produce high quality graphics and audio-visual support for EPA reports, briefings, workshops, and presentations related to this Statement of Work;
- identify, select, and coordinate independent peer reviews for technical analysis products; and
- identification, selection, and coordination of independent peer reviewers for technical and scientific products.

PERFORMANCE REQUIREMENTS

The contractor shall abide by the following performance requirements for each task unless stated otherwise in the work assignment. In all cases, the documents prepared for use by the public shall follow the Plain English style.

Task 1: Risk Assessment Development

- Literature searches, analyses, and technical/benefits evaluations shall be clear, concise, and complete and delivered according to EPA-specified delivery schedules;
- Studies, reviews, evaluations, options, and other written materials resulting from this task shall respond to the appropriate issues identified by EPA, including supporting rationale for recommendations and conclusions;

- All methodologies developed under this task shall be thoroughly tested before submission to EPA to ensure accuracy and functionality of code; and
- Documents prepared under this task shall be technically accurate, defensible, free of errors (e.g., data entry, methodology), and editorially correct (e.g., free of typographic and grammatical errors).

Task 2: Toxicological Summary Development

- Literature searches, analyses, and technical evaluations shall be clear, concise, and complete and delivered according to EPA-specified delivery schedules;
- All toxicological summaries shall be clearly and completely documented;
- Documents prepared under this task shall be technically accurate, defensible, free of errors (e.g., data entry, methodology), and editorially correct (e.g., free of typographic and grammatical errors).

Task 3: Risk Model/Method Development and Support

- All methodologies developed under this task shall be thoroughly tested before submission to EPA to ensure accuracy and functionality of code;
- Revisions to existing models shall be clearly and completely documented including testing and version-control procedures;
- All methodologies developed under this task shall be delivered according to EPA-specified delivery schedules;
- All data/methodologies used in this task shall be clearly and completely documented, and the basis for assumptions clearly stated;
- Background documents, brochures, and other written materials resulting from this task shall be clear, concise, correct and complete, and shall meet stakeholder (for example, state and Federal agency personnel) needs, and be delivered according to EPA-specified delivery schedules;
- Background documents, brochures, and other written materials resulting from this task shall meet the criteria specified in the most current guidelines for electronic data deliverables and the latest design standards and metadata requirements; and
- All models/methods/documents prepared under this task shall be technically accurate, defensible, free of errors (e.g., data entry, methodology), and editorially correct (e.g., free of typographic and grammatical errors).

Task 4: Information Gathering/Analysis

- All materials describing the methodologies used to collect data, including sources of data (published and electronic), shall be clear, concise, and complete and delivered according to EPA-specified delivery schedules;
- All deliverable documents shall clearly demonstrate that the data collected by a particular method are consistent with the scope and application of the method;
- Measures to ensure quality control and quality assurance shall be completely described and implemented in accordance with EPA-established guidelines;
- All analyses, and technical evaluations prepared under this task shall be clear, concise, and complete and delivered according to EPA-specified delivery schedules;

- All materials prepared under this task shall respond to the appropriate issues identified by EPA, including supporting rationale for recommendations and conclusions; and
- All analyses prepared under this task shall be technically accurate, defensible, free of errors (e.g., data entry, methodology), and editorially correct (e.g., free of typographic and grammatical errors).

Task 5: Documentation Preparation

- All deliverable documents describing reviews, modifications, improvements, and development of methodologies resulting from this task shall be clear, concise, and complete and delivered according to EPA-specified delivery schedules;
- Studies, reviews, evaluations, options, and other written materials resulting from this task shall respond to the appropriate issues identified by EPA, including supporting rationale for recommendations and conclusions;
- All reports and graphic material shall be clear, concise, well-organized and complete;
- All documents prepared under this task shall be clearly and completely documented;
- Documents, brochures, and other written materials resulting from this task shall meet the criteria specified in the most current guidelines for electronic data deliverables and the latest design standards and metadata requirements;
- All written materials prepared for use by the public shall follow the "Plain English" style unless specifically stated otherwise in the task order;
- All methodologies developed under this task shall be thoroughly tested before submission to EPA to ensure functionality;
- Peer review deliverables shall describe the procedure used for reviewer selection and detail how appropriate skills and impartiality were ensured; and
- All analyses prepared under this task shall be technically accurate, defensible, free of errors (e.g., data entry, methodology), and editorially correct (e.g., free of typographic and grammatical errors).

Task 6: Regulatory Impact Analysis Support

- All deliverable documents describing reviews, modifications, improvements, and development of methodologies resulting from this task shall be clear, concise, and complete and delivered according to EPA-specified delivery schedules;
- Studies, reviews, evaluations, options, and other written materials resulting from this task shall respond to the appropriate issues identified by EPA, including supporting rationale for recommendations and conclusions;
- All methodologies developed under this task shall be thoroughly tested before submission to EPA to ensure functionality; and
- All analyses prepared under this task shall be technically accurate, defensible, free of errors (e.g., data entry, methodology), and editorially correct (e.g., free of typographic and grammatical errors).

Task 7: Other Technical Support

- All meetings facilitated or planned by the contractor shall be clear, concise and organized in a way to achieve the objectives of the meeting;

- All meeting materials shall be clear, concise and complete;
- All training course materials shall be clear, concise and complete to meet the objectives of the training required;
- The contractor shall obtain an assessment/evaluation of and comments on the training sessions through post training evaluation forms;
- Studies, reviews, evaluations, and other written materials resulting from this task shall respond to the appropriate issues identified by EPA, including supporting rationale for recommendations and conclusions;
- All methodologies developed under this task shall be thoroughly tested before submission to EPA to ensure functionality;
- All analyses prepared under this task shall be technically accurate, defensible, free of errors (e.g., data entry, methodology), and editorially correct (e.g., free of typographic and grammatical errors); and
- Peer reviewers shall be recognized experts in their field and qualified to review the materials submitted for peer review.